DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2014

RANDOX LABORATORIES, LTD.
PAULINE ARMSTRONG, QA/RA MANAGER
55 DIAMOND ROAD
ARDMORE, CRUMLIN, COUNTY ANTRIM, BT29 4QY
UNITED KINGDOM

Re: K142181
Trade/Device Name: Randox Aldolase Calibration Serum
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Secondary
Regulatory Class: II
Product Code: JIT
Dated: August 6, 2014
Received: August 8, 2014

Dear Dr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K142181

Device Name
Randox Aldolase Calibration Serum

Indications for Use *(Describe)*

The Aldolase Calibration Serum is intended for in vitro diagnostic use in the calibration of Aldolase on the Randox RX Daytona and Beckman Coulter AU640 systems.

This device is intended for prescription use only.

Type of Use *(Select one or both, as applicable)*

√ Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY,RANDOX ALDOLASE CALIBRATION SERUM

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2. SUBMITTER NAME AND ADDRESS

Submitter: Randox Laboratories Limited

Address: Randox Laboratories Limited
55 Diamond Road, Crumlin,
County Antrim, BT29 4QY, United
Kingdom.

Contact: Dr. Pauline Armstrong
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E-mail: Pauline.Armstrong@randox.com

Date of Summary Preparation: September 11, 2014

3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k No: k142181

Device Proprietary Name: Randox Aldolase Calibration Serum

Common Name: Aldolase Calibration Serum

Purpose for Submission: New Device

Regulatory Classification: Calibrator,Secondary

Classification: Class II

Panel: Clinical Chemistry (75)

Product Code: JIT (Calibrator, Secondary)
21 CFR Number: 21 CFR 862.1150.

4. PREDICATE DEVICE PROPRIETARY NAMES AND 510 (k) NUMBERS

Predicate Device :
Randox Calibration Serum Levels 2 and 3

510 (k) Numbers: k053153

5. INTENDED USE

The Aldolase Calibration Serum is intended for in vitro diagnostic use in the calibration of Aldolase on the Randox RX Daytona and Beckman Coulter AU640 systems. This device is for prescription use only.

6. DEVICE DESCRIPTION

The Aldolase Calibrator is supplied in a kit containing 3x1ml vials. Each 1 ml vial of lyophilized serum is reconstituted with exactly 1 ml of distilled water and is stable for 5 days when reconstituted and stored at +2°C to +8° C.

The base matrix used for the manufacture of the Aldolase Calibration Serum is Human Serum with added chemicals.

Human source material from which this product has been derived and has been tested at the donor level for the Human Immunodeficiency Virus (HIV1 & HIV2) antibody, Hepatitis B surface antigen (HbsAg) and the Hepatitis C virus (HCV) antibody and were found to be non-reactive based on FDA approved methods.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

7. PREDICATE DEVICE COMPARISON TABLE

TABLE 1: COMPARISON OF RANDOX ALDOLASE CALIBRATION SERUM WITH THE PREDICATE DEVICE

CHARACTERISTICS	ALDOLASE CALIBRATION SERUM *(New Device)*	RANDOX CALIBRATIONSERUM LEVELS 2 AND 3 *k053153* *(Predicate Device)*
INTENDED USE	The Aldolase Calibration Serum is intended for in vitro diagnostic use in the calibration of Aldolase on the Randox RX Daytona and Beckman Coulter AU640 systems. This device is for prescription use only.	For use as a Calibrator in clinical chemistry assays. Randox Calibration Sera are based on lyophilised human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays on a wide range of automatic analysers.
FORMAT	Lyophilised	Same
MATRIX	Human Serum	Same
ANALYTES	1 analyte, Aldolase	43 analytes including Aldolase
STORAGE **(Unopened)**	2 to 8 ^{0}C Until expiration date	Same
OPEN VIAL CLAIM	Reconstituted serum is stable for 5 days at +2°C to +8°C.	Reconstituted serum is stable for 7 days at +2°C to +8°C, 1 month frozen once at 20°C and 8 hours at +25°C.
SIZE	3 x 1ml	20 x 5ml
SHELF LIFE	24 months	36 months

8. SUMMARY OF STABILITY STUDIES

Open vial stabiltiy

Open vial stability of the Aldolase Calibration Serum was assessed by reconstituting the material according to the package insert. Samples were reconstituted and stored at +2 to +8°C for 7 days and tested for Aldolase.

The acceptance criteria state the percentage deviation of reconstituted to fresh should be ≤5%.

Current open vial studies support a reconstituted claim of 5 days when stored at +2°C to +8°C.

Real Time Testing

This study was designed to verify and validate the predicted or desirable shelf life of the Aldolase Calibration Serum. Real Time studies are carried out using procedure RRD-1359. Controls are stored at the routinely stored temperature of +2 - +8°C and at ultra-frozen conditions -75 to -90°C. For real time assessment the routinely stored calibrators are compared to the ultra frozen calibrators at various time points.

The acceptance criteria states that the calibrator recovery for routinely stored compared to ultra-frozen should be within +/-5% deviation and all controls should be within range.

Current Real Time studies support a 2 year shelf life.

9. SUMMARY OF VALUE ASSIGNMENT

1. A mean value for new lots of the Aldolase calibrator are established by performing nested testing of the new calibrator lot against a master lot. The value assignment of the master lot calibrator was derived by nest testing on a suitable clinical Chemistry/Immunoassay Analyzer using a Randox calibrator with established consensus values or an International reference preparation (IRP) where available and applicable. The master lot values must fall within the predetermined acceptance criteria.

2. The value assignment was determined by analyzing ten replicates of the test calibrator on two or more systems and the mean, SD and CV calculated for each lot before release to the user. The acceptance criteria states the precision measured by the CV should be less than or equal to 3%.

Aldolase Calibration Serum	N	Mean (U/L)	System Specific Value (U/L)	CV %
RX Daytona	10	18.4	18.7	2.2
Beckman Coulter AU640	10	19	18.7	1.8

10. TRACEABILITY

ANALYTE	**SUPPLIER**	**PRODUCT NUMBER**	**ORIGIN**	**SOURCE**
Aldolase	Sigma	A2714	Rabbit Muscle	Commercial Source, added volumetrically

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate device.